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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
TOWA, RENE T	

ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 06/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/790,416	BURBANK ET AL.	
	Examiner	Art Unit	
	Rene Towa	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 March 2006*.

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,29,31-33 and 40-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 29, 31-33, and 40-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This Office action is responsive to an amendment filed March 16, 2006. Claims 1, 29, 31-33 and 40-51. Claims 1, 29, 33, 40 and 45-49 are amended. No new claim has been added. No claim has been cancelled.

Drawings

2. The objections are withdrawn due to amendments.

Specification

3. The disclosure is objected to because of the following informalities:

At page 1, Applicant has not disclosed the current status of the related applications.

Appropriate correction is required.

Claim Objections

4. The objections are withdrawn due to amendments.

Claim Rejections - 35 USC § 112

5. The rejections are withdrawn due to amendments.

Claim Rejections - 35 USC § 102

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 1, and 40-51 are rejected under 35 U.S.C. 102(e) as being anticipated by Kieturakis (US Patent No. 5,794,626).

In regards to claim 1, Kieturakis discloses a biopsy instrument 5 for retrieving body tissue, having a longitudinal axis and comprising:

a distal end 45 adapted for entry into a patient's body;

an electrosurgical cutting element 10 energizable by radio frequency energy disposed on a distal portion of the instrument, which is actuatable between a radially retracted position and a radially extended position, relative to said axis, and which is movable in said radially extended position to isolate a desired tissue specimen from surrounding tissue by defining a peripheral margin about said tissue specimen, and

an encapsulation component 15 capable of encapsulating the isolated tissue specimen before its removal from the patient's body (see figs. 2-3 & 12).

It is noted that the term "electrosurgical," absent any special definition set forth in the specification, fails to define a structural difference between Applicant's cutting element and the flex-blade cutter of Kieturakis; for example, the flex-blade cutter is a surgical instrument, which is provided with electrical power 142 in order to generate a rotational movement of the cutters. Moreover, it is noted that the flexors 15 of Kieturakis could be made out of stainless steel (see column 4/lines 1-9), which makes them capable of being energized by radio frequency energy. As such, the flexors 15 are energizable by radio frequency energy.

In regards to claim 40, Kieturakis discloses an instrument assembly 5 for isolating a tissue specimen from an intracorporeal site, comprising:

a. an elongate shaft 40 which has a longitudinal axis and a distal end 45; and

b. an electrosurgical tissue cutting component 10 energizable by radio frequency energy which is radially extendable from a retracted position to an extended

position and which is capable of creating a peripheral boundary about the tissue specimen and electrosurgically isolating a desired tissue specimen from surrounding tissue at the site; and

c. a tissue collection component 15 coupled to the shaft 40 which is capable of encapsulating the isolated tissue specimen from the surrounding tissue at the site (see fig. 12);

wherein the tissue collection component 15 is capable of maintaining the encapsulated tissue specimen intact (see fig. 12);

wherein the tissue cutting component 10 is longitudinally disposed on the elongate shaft 40 proximal of the distal end 45 of the shaft 40;

wherein the tissue cutting component 10 is configured to be rotated at least in part about the longitudinal axis in the radially extended position to isolate the tissue specimen;

wherein both the cutting component 10 and the tissue collection component 15 are movable from a retracted position to an expanded position (see figs. 2-3 & 12);

It is noted that the term "electrosurgical," absent any special definition set forth in the specification, fails to define any structural difference between the cutting element and the flex-blade cutter of Kieturakis; for example, the flex-blade cutter is a surgical instrument, which is provided with electrical power 142 in order to generate a rotational movement of the cutters.

In regards to claims 45-48, Kieturakis discloses an excisional device 5 for cutting and removing a specimen of breast tissue, comprising:

a shaft 40

a tissue electrosurgical cutting component 10 energizable by radio frequency energy coupled to the shaft 40 and configured to cut the specimen of breast tissue from surrounding breast tissue;

a tissue collection component 15 coupled to the shaft 40 which is capable of encapsulating the cut specimen and maintaining the encapsulated specimen intact, both the cutting component 10 and the tissue collection component 15 being movable from a retracted position to an expanded position;

wherein at least one tissue collection component 15 has a proximal end 23 and a distal end 24 and which is configured to move one end closer to the other end to effect radial extension from the retracted position to the radial extended arcuate position (see figs. 2-3);

wherein the tissue collection component 15 is configured so that the distal end 24 is fixed and the proximal end 23 moves toward the distal end 24;

wherein the tissue collection component 15 and the tissue-cutting component 10 are configured to expand and retract together (see figs. 2-3).

In regards to claims 49-51, Kieturakis discloses an instrument 5 for encapsulating and removing a tissue specimen from a patient's body, comprising:

a. an elongate shaft 40 which has a distal end 45 a longitudinal axis;

b. an electrosurgical tissue cutting component 10 energizable by radio frequency energy which is disposed on a distal portion of the elongate shaft 40, which is radially extendable from a retracted position to an extended position, relative to the

longitudinal axis, which has an arcuate shape in the extended position and which is movable in the radially extended position about the longitudinal axis to isolate a desired tissue specimen from surrounding tissue by defining a peripheral margin about said tissue specimen (see figs. 2-3 & 12); and

c. an encapsulation component 15 capable of encapsulating the tissue specimen after it has been isolated from surrounding tissue and removing the tissue specimen from the patient's body intact;

wherein the instrument 5 has a distal tissue-cutting element 45 with a linear cutting surface disposed on the distal end of the shaft 40 to facilitate accessing the tissue specimen within the patient's body;

wherein the encapsulation component 15 has a plurality of encapsulation elements, which are radially extendable from a retracted position to an extended position (see figs. 2-3 & 12).

8. Claims 1, 40-49 and 51 are rejected under 35 U.S.C. 102(e) as being anticipated by Patterson et al. (US Patent No. 5,941,869).

In regards to claim 1 Patterson et al. disclose an instrument for retrieving body tissue, having a longitudinal axis and comprising:

a distal end adapted for entry into a patient's body;

an electrosurgical cutting element (136, 138) (see figs. 9-10; column 6/lines 24-31; column 8/lines 42-44; column 9/lines 17-21) energizable by radio frequency energy disposed on a distal portion of the instrument, which is actuatable between a radially retracted position and a radially extended position, relative to said axis, and which is

capably movable in said radially extended position to isolate a desired tissue specimen from surrounding tissue by defining a peripheral margin about said tissue specimen, and

an encapsulation component 120 configured to encapsulate the isolated tissue specimen before removal of the specimen from the patient's body (see figs. 7-9).

In regards to claim 40, Patterson et al. disclose an instrument assembly for isolating a tissue specimen from an intracorporeal site, comprising:

a. an elongate shaft 126 which has a longitudinal axis and a distal end (see fig. 7); and

b. an electrosurgical tissue cutting component (136, 138) energizable by radio frequency energy which is radially extendable from a retracted position to an extended position and which is configured to create a peripheral boundary about the tissue specimen and electrosurgically isolate a desired tissue specimen from surrounding tissue at the site (see figs. 9-10; column 6/lines 24-31; column 8/lines 42-44; column 9/lines 17-21); and

c. a tissue collection component 120 coupled to the shaft 126 which is capable of encapsulating the isolated tissue specimen from the surrounding tissue at the site (see figs. 2-3 & 7);

wherein the tissue collection component 120 is capable of maintaining the encapsulated tissue specimen intact (see fig. 7);

wherein the tissue cutting component (136, 138) is longitudinally disposed on the elongate shaft 126 proximal of the distal end of the shaft 126;

wherein the tissue cutting component (136, 138) is configured to be rotated at least in part about the longitudinal axis in the radially extended position to isolate the tissue specimen (see figs. 9-10; column 6/lines 24-31; column 8/lines 42-44; column 9/lines 17-21);

wherein both the cutting component (136, 138) and the tissue collection component 120 are movable from a retracted position to an expanded position (see figs. 2-3 & 7; column 4/lines 13-40);

In regards to claims 45-48, Patterson et al. disclose an excisional device, comprising:

a shaft 126

a tissue electrosurgical cutting component (136, 138) energizable by radio frequency energy coupled to the shaft 126 and capable of cutting a specimen of breast tissue from surrounding breast tissue;

a tissue collection component 120 coupled to the shaft 126 which is capable of encapsulating the cut specimen and maintaining the encapsulated specimen intact, both the cutting component (136, 138) and the tissue collection component 120 being movable from a retracted position to an expanded position;

wherein at least one tissue collection component 120 has a proximal end and a distal end and which is configured to move one end closer to the other end to effect radial extension from the retracted position to the radial extended arcuate position (see figs. 2-3 & 7);

wherein the tissue collection component 120 is configured so that the distal end 120 is fixed and the proximal end moves toward the distal end (see figs. 2-3 & 7);

wherein the tissue collection component 120 and the tissue-cutting component (136, 138) are configured to expand and retract together.

In regards to claims 49 and 51, Patterson et al. disclose an instrument for encapsulating

and removing a tissue specimen from a patient's body, comprising:

a. an elongate shaft 126 which has a distal end a longitudinal axis;

b. an electrosurgical tissue cutting component (136, 138) energizable by radio frequency which is disposed on a distal portion of the elongate shaft 126, which is radially extendable from a retracted position to an extended position, relative to the longitudinal axis, which has an arcuate shape in the extended position and which is movable in the radially extended position about the longitudinal axis to isolate a desired tissue specimen from surrounding tissue by defining a peripheral margin about said tissue specimen (see figs. 7 & 9-10; column 6/lines 24-31; column 8/lines 42-44; column 9/lines 17-21; column 4/lines 13-40); and

c. an encapsulation component 120 capable of encapsulating the tissue specimen after it has been isolated from surrounding tissue and removing the tissue specimen from the patient's body intact;

wherein the encapsulation component 120 has a plurality of encapsulation elements 122, which are radially extendable from a retracted position to an extended position (see figs. 2-3 & 7).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.,

10. Claims 29 and 31-32 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kieturakis (US Patent No. 5,794,626).

In regards to claims 29 & 31-33, Kieturakis discloses a method for retrieving a tissue specimen from a patient's body, comprising:

inserting into the patient's body an instrument 5 having a distal end 45, a longitudinal axis, and an axially disposed cutting element 10 so that the distal end 45 is disposed in a tissue region from which the tissue specimen is taken;

radially extending the cutting element 10 so that a portion thereof is radially outwardly spaced from the axis of the instrument 5;

rotating the cutting element 10 about the axis to cut the tissue and create a peripheral boundary about the tissue specimen, to isolate the tissue specimen from surrounding tissue in the tissue region; and

encapsulating the isolated tissue specimen before removing the specimen from the patient's body (see column 2/lines 35-60);

wherein the encapsulating step further includes radially expanding at least one encapsulating element 15 so that a portion thereof is radially outwardly spaced from the

axis of the instrument 5 and rotating the instrument 5 about its axis so that the at least one encapsulating element 15 encloses the tissue specimen (see column 2/lines 48-53);

wherein said at least one encapsulating element 15 comprises a plurality of bands which are disposed axially along said instrument 5 (see fig. 12).

It is noted that the term "electrosurgical," absent any special definition set forth in the specification, fails to define a structural difference between Applicant's cutting element and the flex-blade cutter of Kieturakis; for example, the flex-blade cutter is a surgical instrument, which is provided with electrical power 142 in order to generate a rotational movement of the cutters. Moreover, although Kieturakis does not expressly teach that the flexors 15 are radio frequency energized, it is noted that the flexors 15 of Kieturakis could be made out of stainless steel (see column 4/lines 1-9), which makes them capable of being energized by radio frequency energy. As such, the flexors 15 are energizable by radio frequency energy. Furthermore, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a method comprising radio frequency energizable cutters since the Applicant has not disclosed in the claims that having the radio frequency energizable cutters is used for a particular purpose (i.e. no active step of using the radio frequency energy) since such a modification would amount to a design choice (i.e. the method could be carried out with another device that is not radio frequency energizable).

11. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kieturakis (626) in view of Kanner et al. (US Patent No. 5,392,790).

Kieturakis discloses a method, as described above, that teaches all the limitations of the claim except Kieturakis does not teach proximally withdrawing an instrument with the encapsulated tissue specimen from the patient's body. However, Kanner et al. disclose a method comprising proximally withdrawing an instrument 20 with the encapsulated tissue specimen from the patient's body (see figs. 11-13). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a method similar to that of Kieturakis with a method step similar to that of Kanner in order to remove the severed tissue (see Kanner, column 5/lines 2-22).

Response to Arguments

12. Applicant's arguments filed March 20, 2006 have been fully considered but they are not persuasive. Applicant contends that Kieturakis does not teach or disclose a cutter which uses radiofrequency energy to isolate a desired tissue specimen. Applicant contends that Patterson does not teach a device that isolates tissue by defining a peripheral boundary about the specimen or maintains the specimen intact when removing the specimen from the body. These arguments have been considered and have not been deemed persuasive.

In regards to the Applicant's argument that Kieturakis does not teach or disclose a cutter, which uses radiofrequency energy to isolate a desired tissue specimen, the Examiner respectfully traverses. The Examiner notes that the claim language only requires a radio frequency energizable apparatus as opposed to an apparatus that is energized by radio frequency. In response to applicant's argument that the references

fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., that the cutter uses radiofrequency energy to isolate a desired tissue specimen) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). As such, the Examiner submits that Kieturakis discloses a device that comprises radio frequency energizable cutters 15 (see rejections supra).

Applicant's arguments that Patterson does not teach a device that isolates tissue by defining a peripheral boundary about the specimen or maintaining the specimen intact when removing the specimen from the body have been fully considered and are persuasive. The rejections of claims 29 and 31-33 have been withdrawn. However, the Applicant is reminded that, unlike the method claim limitations, a recitation of the intended use of the claimed invention (i.e. a device or apparatus) must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. As such, the device of Patterson, although not expressly taught, is fully capable of defining a peripheral boundary about the specimen or maintaining the specimen intact when removing the specimen from the body (see rejections supra). As such, the rejections of claims 1, 40-49 and 51 in view of Patterson et al. are maintained.

Conclusion

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rene Towa whose telephone number is (571) 272-8758. The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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